

105 CMR 680.000: PHOSPHATES IN HOUSEHOLD CLEANSING PRODUCTS

Section

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680.001: Purpose

105 CMR 680.000 is set forth for the purpose of implementing and interpreting the requirements of M.G.L. c. 111, § 5R which limits the sale, distribution and use in the Commonwealth of household cleansing products containing phosphorus.

680.002: Authority

105 CMR 680.000 is adopted pursuant to M.G.L. c. 111, §§ 3, 5, and 5R.

680.003: Definitions

As used in 105 CMR 680.000, the following terms shall have the following meanings, unless the context clearly requires otherwise:

Act means M.G.L. c. 111, § 5R.

Commercial establishment means any premises used for the purpose of carrying on or exercising any trade, business, profession, vocation, or commercial or charitable activity including but not limited to carwashes, laundries, hospitals, including veterinary facilities, biological research facilities, hotels, and food or restaurant establishments.

Commissioner means the Commissioner of the Department of Public Health or the head of such other appropriate state agency to which the Department's powers and duties under 105 CMR 680.000 are transferred by lawful agreement.

Department means the Department of Public Health or such other appropriate state agency to which the Department's powers and duties under 105 CMR 680.000 are transferred by lawful agreement.

Environmental surface cleanser means cleansers used for cleansing of floors, walls, tables, windows, countertops, sinks and other surfaces in buildings.

Household cleansing product means any product, soap, or detergent used for domestic or commercial cleaning purposes, including, but not limited to, the cleansing of automobiles, fabric, dishes, food utensils and household premises and premises in commercial establishments. Household cleansing products shall not include:

- (a) foods, drugs and cosmetics, including personal care items such as toothpaste, shampoo, and hand soap;
- (b) products regulated under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.* as amended;
- (c) products labeled, advertised, marketed and distributed for use primarily as polishes; and
- (d) liquid products labeled, advertised, marketed and distributed for use primarily as environmental surface cleaners in commercial establishments and which have elemental phosphorus content that does not exceed 0.5% of the product by weight and more than 0.1% in the use dilution.

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Laundry means commercial laundries and laundries in commercial establishments and in institutional facilities such as hospitals and nursing homes.

Person means any proprietor of a commercial establishment, corporation, municipality, the Commonwealth of Massachusetts or any of its departments, agencies, subdivisions or authorities, and any partnership, unincorporated association or other legal entity.

Phosphorus means elemental phosphorus.

Reasonably available alternative means a cleansing product used or able to be used in connection with the same industrial manufacturing, production or assembling processes as the household cleansing product for which an industrial use exemption is sought which:

- (a) contains less phosphorus than that household cleansing product;
- (b) is reasonably comparable to that household cleansing product in terms of effectiveness for its intended industrial uses;
- (c) is no more harmful to the environment than that household cleansing product; and
- (d) is reasonably available in terms of cost and market availability to users or potential users in the Commonwealth.

Trace quantities means an incidental amount of a chemical which is not part of the household cleaning product formulation, is present only as a consequence of manufacturing and does not exceed 0.5% of the content of the product by weight.

Trace quantity of phosphorus means an incidental amount of phosphorus which is not part of the household cleaning product formulation, is present only as a consequence of manufacturing, or to assure product or container stability, and does not exceed 0.5% of the content of the product by weight, expressed as elemental phosphorus.

Trade Secret Information means any formula, plan, production data or other information about a household cleansing product which its manufacturer considers to be and treats as proprietary information, which is not available to the public by any other source, and disclosure of which would be seriously prejudicial to the manufacturer's economics of operation or would put the manufacturer at a significant competitive disadvantage.

Use dilution means the minimum or lowest dilution of a household cleansing product recommended by the manufacturer in its product materials for that household cleansing product.

680.004: Sale, Offering, Distribution and Use of Household Cleansing Products Containing Phosphorus

(1) On and after July 1, 1994, no person shall sell, distribute, offer or expose for sale at wholesale or retail, or use in a commercial establishment in the Commonwealth, household cleansing products which contain a phosphorus compound in excess of a trace quantity except those household cleaning products used in dishwashing machines or commercial laundries or for cleansing medical and surgical equipment or food and beverage processing equipment.

(2) On and after July 1, 1994, no person shall sell, distribute, offer or expose for sale at wholesale or retail, or use in a commercial establishment in the Commonwealth, household cleansing products used in dishwashing machines or laundries or for cleansing medical and surgical equipment or food and beverage processing equipment which contain a phosphorus compound in excess of 8.7% by weight expressed as elemental phosphorus.

(3) No person shall offer for sale, in the Commonwealth, household cleansing products which violate 105 CMR 680.004 by advertising such products in a sales catalogue printed or distributed on or after July 1, 1994; catalogues printed or distributed on or after that date shall identify such household cleansing products included therein as "not for sale or distribution in Massachusetts".

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A household cleansing product shall not be deemed to be distributed, sold, or offered or exposed for sale in the Commonwealth because of inclusion of the household cleansing product in a sales catalog printed and distributed before July 1, 1994, provided however that the household cleansing product is not sold or distributed in the Commonwealth after that date.

(4) The provisions of 105 CMR 680.004 shall not apply to household cleansing products which:

- (a) are labeled and advertised, marketed and distributed for use in agricultural production and for cleansing agricultural equipment including dairy equipment; or
- (b) contain sodium phosphate and are labeled and advertised, marketed and distributed for clean-up following lead paint removal or the cleaning of lead dust; or
- (c) are used for hand cleaning glassware and other utensils used in the hospitality industry and which have elemental phosphorus content that does not exceed 16% of the product by weight and more than 0.03% in use dilution.

(5) The following products are not household cleansing products: products used as water softening chemicals, anti-scale chemicals or corrosion inhibitors intended for use in closed systems, such as boilers, air conditioners, cooling towers or hot water systems.

(6) The provisions of 105 CMR 680.004 shall not apply to any municipality or the Commonwealth or any department, agency, authority or subdivision of the Commonwealth, or any agent thereof, when in performance of official duties relating to conducting procedures necessary for safety tests to determine the presence of lead or other compounds.

(7) The provisions of 105 CMR 680.004 shall not apply to household cleansing products used primarily in industrial, manufacturing, or assembling process for which an industrial use exemption has been granted under 105 CMR 680.007.

(8) Nothing in 105 CMR 680.004 shall prohibit a manufacturer or distributor of a household cleansing product from selling, distributing, offering or exposing for sale at wholesale a household cleansing product which exceed the limitations of 105 CMR 680.004 if the household cleansing product is sold to an out-of-state purchaser for use outside of the state.

680.005: Record keeping and Reporting Requirements

(1) Within 30 days of a request by the Commissioner, the manufacturer of any household cleansing product distributed, sold, or offered for sale in the Commonwealth shall submit to the Department such information regarding such products as the Commissioner may require, in such form as is required by the Commissioner. For each household cleansing product the manufacturer shall be prepared to provide, at a minimum, the following information:

- (a) the amount of elemental phosphorus by weight as measured to the nearest 1/10th of 1%, and documentation supporting the manufacturer's determination of the quantity of the phosphorous in the household cleansing product;
- (b) a list naming each ingredient in the household cleansing product, by CAS number or generic chemical name, which equals or exceeds 5% of the contents of the product by weight and specifying the content by weight of each ingredient to the nearest percent.
- (c) a list naming each ingredient in the household cleansing product which does not exceed 5% of the product by weight, but which is present in more than a trace quantity, by either CAS number or generic chemical name which conforms with generally accepted rules of chemical nomenclature; and
- (d) a listing of all research, reports, studies and investigations on the nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health and the environment of such ingredients or such product.
- (e) the name, job title, address, and telephone number of the individual assigned by the manufacturer whom the Department may contact for any additional information relating to the manufacturer's household cleansing product.

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(2) For a period of 60 days after the household cleansing product is no longer distributed, sold or offered for sale in the Commonwealth, the manufacturer shall have available the information that could be requested under 105 CMR 680.005(1).

(3) When submitting any information requested by the Commissioner under 105 CMR 680.005(1), the manufacturer may provide the information subject to a claim of trade secret status subject to a claim of 105 CMR 680.007.

680.006: Industrial Use Exemptions

(1) At any time, the manufacturer of a household cleansing product used primarily in industrial manufacturing, production or assembling processes, or any user of such product, may apply to the Commissioner to have the product exempted from the sale, offering, distribution and use prohibitions of 105 CMR 680.004.

(2) Applications for industrial use exemptions shall include:

(a) the name of the household cleansing product for which the exemption is being sought with the amount of elemental phosphorus by weight as measured to the nearest 1/10th of a percent;

(b) a statement or list specifying the industrial, manufacturing, production or assembling processes known to the applicant in connection with which the household cleansing product is or could be used including any specific purposes for which the applicant plans to use the household cleansing product;

(c) a listing of all recommended and potential domestic, commercial and industrial uses of the household cleansing product known to the applicant;

(d) any evidence supporting the argument that the household cleansing product is used primarily in industrial manufacturing, production and assembling processes;

(e) a listing of other cleansing products known to the applicant which are or could potentially be used for the same industrial manufacturing, production and assembling processes as the household cleansing product for which the exemption is sought; and

(f) evidence supporting the argument that there exist no reasonably available alternative, within the meaning of 105 CMR 680.000, to the household cleansing product for which the exemption is sought.

(3) Within ten days of receipt of an application, the Commissioner shall determine if the application is complete. The Commissioner shall return incomplete applications.

(4) The Commissioner may request additional information about the household cleansing product or its alternatives from the manufacturer or user to substantiate statements made in the application. The application shall not be considered complete until all the information required by 105 CMR 680.006(2) and any additional information requested by the Commissioner under 105 CMR 680.006(2) has been submitted to the Commissioner.

(5) The Commissioner may also request and/or receive and consider, in connection with an application for an industrial use exemption, information about the household cleansing product or its alternatives from persons and sources other than the manufacturer or user seeking the exemption.

(6) Within 45 days of receiving a completed application, the Commissioner shall issue his decision either to grant or to deny an industrial use exemption for that household cleansing product. His decision shall include a statement of reasons supporting his decision. If the Commissioner fails to deny an application within this 45 day period, the application shall be deemed approved for a period of one year.

(7) (a) The Commissioner shall grant an industrial use exemption for a household cleansing product only if there is no reasonably available alternative to that product.

(b) A product shall be deemed to be a reasonably available alternative to a household cleansing product for which an industrial use exemption is sought if that product:

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1. is or may be used in the same industrial manufacturing, production or assembling processes as the household cleansing product;
2. contains less phosphorus than the household cleansing product;
3. is reasonably comparable to the household cleansing product in terms of effectiveness for the intended industrial uses;
4. is no more harmful to the environment than the household cleansing product;
5. is reasonably available in terms of cost, provided that in making this determination, the impact of a higher cost alternative product on the competitive situation of the industrial user or users shall be considered by the Commissioner; and
6. is reasonably available in terms of market availability to users or potential users in the Commonwealth.

(c) The following household cleansing products do not have any reasonably available alternatives and are therefore exempt from the sale, offering, distribution and use prohibitions of 105 CMR 680.004:

1. household cleansing products used for cleansing equipment used by manufacturers of carbonated or other beverages the formulation of which contains up to 15% phosphoric acid;
2. household cleansing products used by manufacturers in the preparation of the surface of metals; and
3. household cleansing products used in metal treatment, industrial metal cleaning, and textile processing.

(d) The following products shall not be considered to be reasonably available alternatives to household cleansing products:

1. products containing Chloroflorcarbons or Chloroflorocarbon precursors;
2. products containing greater than 10% arsenic;
3. products containing hexavalent chromium-based cleansers; and
4. products containing petroleum distillate-based solvents.

(8) Within 30 days of receipt of a decision, a manufacturer or user of a household cleansing product can request the Commissioner to reconsider a denial of an industrial use exemption. Within 15 days of such a request for reconsideration, the Commissioner shall issue a final decision. If no request for reconsideration is filed, or if the original decision was to grant the industrial use exemption, the original decision shall constitute the final decision of the Commissioner.

(9) An industrial use exemption, if granted, shall extend only to the use of the product in industrial manufacturing, production and assembling processes. The prohibition on the sale, offering, distribution and use of household cleansing products set forth in 105 CMR 680.004 shall apply to all other uses of the household cleansing product.

(10) An industrial use exemption, if granted, shall be for a limited period of time. The Commissioner shall, on a case by case basis, establish a reasonable time period for each industrial use exemption, which period shall in no event exceed ten years. In determining the appropriate time period the Commissioner shall consider, among other things, the likelihood of, and the anticipated time frame for, the future availability of a reasonably available alternative to the household cleansing product. Final decisions granting industrial use exemptions shall clearly set forth the expiration date of the exemption.

(11) Any manufacturer or user of a household cleansing product for which an industrial use exemption has been previously granted who seeks to renew an industrial use exemption must file an application for renewal of the exemption with the Commissioner at least 90 days prior to the expiration of the industrial use exemption. The application shall contain the same information required for a new application under 105 CMR 680.006(2). The Commissioner shall issue a final decision granting or denying the renewal application within 90 days of receipt of a completed application or by the expiration date of the prior industrial use exemption, whichever is later. In all other respects, the renewal application shall be subject to the procedures and standards set forth in 105 CMR 680.006 governing original applications.

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(12) The prohibitions on the sale, offering, distribution and use of household cleansing products set forth in 105 CMR 680.004 shall not apply to household cleansing products which are the subject of a completed industrial use exemption application or a completed renewal application pending before the Commissioner, so long as the application is pending and for a period of 120 days after the Commissioner has issued a final decision denying the exemption. At the end of the 120 day period, the prohibitions of 105 CMR 680.004 shall apply to that household cleansing product. The 120 day period may be extended by the Commissioner when there is good cause to grant such an extension.

(13) The Commissioner shall keep and maintain a list of all household cleansing products which have received industrial use exemptions. The Commissioner shall make the list available to the public upon request.

680.007: Availability of Household Cleansing Product Information and Protection of Trade Secret Information

(1) The Department shall make all of the household cleansing product information obtained by it pursuant to the requirements of 105 CMR 680.000, with the exception of information described in 105 CMR 680.007(2), available to the public for inspection and copying unless the manufacturer has filed a notice of claim of trade secret status with respect to that information in accordance with 105 CMR 680.007(3), and the Commissioner has not made a determination of non-confidentiality with respect to that information in accordance with 105 CMR 680.007(8), in which case the Department shall keep the information confidential.

(2) The information described in 105 CMR 680.005(1)(b) and (c) is deemed to be trade secret information and shall not be released by the Department.

(3) The manufacturer may file a notice of claim of trade secret status with respect to any information it submits to the Department under 105 CMR 680.000. In order to do so, the manufacturer need only file with the Department a document entitled "Notice of Claim of Trade Secret Status" which briefly and summarily identifies the information the manufacturer believes to be trade secret information along with two copies of each document containing such information that was requested by the Department, one of which contains the full information requested by the Department and is enclosed in an envelope marked "Confidential" and the other of which has been redacted to eliminate the purported trade secret information.

(4) The Department shall inform any person requesting information which is subject to a manufacturer's notice of claim of trade secret status that the information is not available because it is subject to such notice of claim, but that the person may request the Department under 105 CMR 680.007(5) to make a determination that the information is non-confidential. The Department shall also supply that person, upon request, with a copy of the manufacturer's notice of claim of trade secret status.

(5) Any person may challenge a manufacturer's claim of trade secret status by filing a "Petition to Remove Trade Secret Status" with the Department. The petition shall clearly identify the information sought by the petitioner and contain a statement of the reasons why the information should not be considered trade secret information.

(6) Upon receipt of any petition to remove trade secret status filed under 105 CMR 680.007, the Department shall forward a copy of the petition to the manufacturer whose information is being sought by the petitioner.

(7) The manufacturer may, within 15 days of receipt of a copy of a petition to remove trade secret status from the Department, file evidence and/or arguments in writing in support of its claim of trade secret status. Failure to submit any such evidence and/or arguments in writing shall be deemed a waiver of the manufacturer's claim of trade secret status.

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(8) Within 20 days after the expiration of the 15 day period referred to in 105 CMR 680.007(7), the Department shall issue a determination of confidentiality upholding the manufacturer's claim of trade secret status or a determination of non-confidentiality overruling the manufacturer's claim of trade secret status, in accordance with the standards set forth in 105 CMR 680.007(9). Copies of any such determination shall be mailed to the petitioner and the manufacturer. In the event the Department issues a determination of non-confidentiality it shall not release the requested information to the petitioner until 15 business days after the issuance of the determination.

(9) The Department shall uphold the manufacturer's claim of trade secret status if it determines that the information in question is trade secret information. The Department shall overrule the manufacturer's claim of trade secret status if it determines that the information in question is not trade secret information. The Department shall determine that information is trade secret information if it finds that disclosure of the information would be seriously prejudicial to the manufacturer's economics of operation or would put the manufacturer at a competitive disadvantage.

(10) Any person aggrieved by a determination of confidentiality or non-confidentiality issued by the Department may seek relief therefrom in any court of competent jurisdiction, as provided by the laws of the Commonwealth.

680.008: Penalties

(1) Any person who uses a household cleansing product in violation of 105 CMR 680.000 shall be punished by a fine of not less than \$25.00 and not more than \$100.

(2) Any person who sells, distributes or offers for sale at retail or wholesale a household cleansing product in violation of 105 CMR 680.004 shall be punished by a fine of not less than \$1,000 and not more than \$5,000 for each 24 hour period during which a violation occurs.

(3) The department may seize any household cleansing product held for sale or distribution in violation of 105 CMR 680.000. The person selling or distributing the household cleansing product shall forfeit it.

680.009: Severability

If any provisions of 105 CMR 680.000 are held invalid for any reason whatsoever, such declaration shall not effect any other portion of 105 CMR 680.000, which shall remain in full force and effect, and to this end, the provisions of 105 CMR 680.000 are hereby declared severable.

REGULATORY AUTHORITY

105 CMR 680.000: M.G.L. c. 111, § 5R.

NON-TEXT PAGE